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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,301	07/23/2003	T. William Hutchens	016866-002220US	1861

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EXAMINER	
WESSENDORF, TERESA D	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,301	HUTCHENS ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27 and 36-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27 and 36-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group V11, claim 27, (drawn to a method for detecting translation of a polynucleotide) in the reply filed on 9/28/04 is acknowledged.

Applicants' election of the subgenus of anionic adsorbents, such as cationic exchange adsorbents, and the species of carboxylate anionic adsorbents, with traverse in the reply on 2/14/05 is acknowledged.

In view of applicants' arguments, all of the species drawn to the adsorbents will be examined.

Status of Claims

Claims 27 and 36-44 are pending and under examination.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors (e.g., spelling, grammar and etc.). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27 and 36-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the genus of the invention.

The specification, at the time of filing, does not describe a method for detecting translation of a polynucleotide from the produced polypeptide. There is no correlation as to the polypeptide obtained to the translation of the polynucleotide. The specification provides in general terms the different embodiments of the invention. At paragraph bridging pages 13 and 14, the specification states that another aspect of the invention provides a method for detecting translation of a

polynucleotide. One method comprises the steps of: a) providing a substrate
comprising an adsorbent for use in desorption spectrometry; b) contacting the substrate with the polynucleotide encoding a polypeptide and with agent B for in vitro translation of the polynucleotide whereby the polypeptide is produced; c) exposing the substrate to an eluant to allow retention of the polypeptide by the adsorbent; and d) detecting retained polypeptide by desorption spectrometry. Detection of the polypeptide provides detection of translation of the polynucleotide. The general aspects of the invention do not correlate to a specific description of a single species of each of the different compounds and/or reagents. The encoding polynucleoide, the polypeptide, adsorbent and /or the reagent use in the method cover such huge scope. It is well known in the art that because of the degeneracy of the genetic code, one cannot predict whether a polypeptide is the desired product that is derived from a polynucleotide translation. Other factors such as fragmentation of the polypeptide, the presence of impurities or interfering substances can affect the method. In biotechnological invention one cannot necessarily make a priori statement without the benefit of experimental studies. There may be unpredictability in the results obtained for one species, let

alone, from a genus as broadly claimed. Adequate disclosure, like enablement, requires representative examples, which provide reasonable assurance to one skilled in the art that the compounds falling within the scope both possess the alleged utility and additionally demonstrate that applicant had possession of the full scope of the claimed invention. See In re Riat (CCPA 1964) 327 F2d 685, 140 USPQ 471; In re Barr. (CCPA 1971) 444 F 2d 349, 151 USPQ 724 (for enablement) and University of California v. Eli Lilly and Co. (for disclosure). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as structures, figures, diagrams, and formulas that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir.1997). There is not a single structure for any or all of the compounds encompassed in the broad scope of the claimed method.

Claims 27 and 36-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include:

(1) the breadth of the claims,
(2) the nature of the invention,
(3) the state of the prior art,
(4) the level of one of ordinary skill;
(5) the level of predictability in the art,
(6) the amount of direction provided by the inventor,
(7) the existence of working examples, and
(8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.
In re Wands, (U.S.P.Q. 2d 1400 (CAFC 1988).

1). The specification fails to give adequate direction and guidance in how to readily go about determining which polynucleotide translates into a polypeptide in situ on an adsorbent. It does not teach with specificity the detection of the polynucleotide from the polypeptide produced from the translation. It does not enable how a translation of a polynucleotide in situ in an adsorbent can be accomplished. It does not describe the kind of translation polynucleotide and/or polypeptide, adsorbent and reagents employ in the method.

2). The specification failed to provide a single working example for the translation of a polynucleotide and detection of the polypeptide presumably obtained from the translation by the polynucleotide. There are just too many and different

combinations of the compounds and reagents use in the method as well as other undefined variables.

3). The breadth of the claims encompasses a large diversity of translation polynucleotide, polypeptide, adsorbents and reagents. It is well known in the art that the diversity of the inserts in a vector as the claimed bacteriophage or host is not easily estimated. It may be for example, that only a small subset of possible peptide sequences are presented efficiently by a particular expression system. And, it is not always easy to follow the expression of peptides in particular cells; for example, to know whether or not a specific cell is expressing a member of the insert, especially for biological methods.

4). The state of the prior art is such that techniques or methods are specifically applied or adapted for a known or defined structure of a translation polynucleotide and its specifically expressed product.

5). The art is inherently unpredictable because it is not possible to predict that even with a predetermined translation polynucleotide the one that would specifically translates to a desired polypeptide. Whether the polypeptide produced is adsorbed in a certain type of adsorbent or the polypeptide correlates to the polynucleotide from which it is translated. It is generally known that there are still no rules that have

emerged that allow the translation of a polynucleotide to be related to sequence in any simple fashion (even as applied to the actual compounds).

6). Because the art is unpredictable, applicants' specification reasonably would not have assured persons skilled in the art to the numerous undefined variables of the claimed method. Applicants do not adequately enable persons skilled in the art to readily determine such. Applicants need not guarantee the success of the full scope of the claimed invention. However, skilled artisans are provided with little assurance of success.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27 and 36-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). The method in step c as to the translating the polynucleotide in situ on the adsorbent is unclear as to how

this is done since this is not positively recited in the specification. The step is at odds with the specification e.g., paragraph bridging pages 3 and 4, above.

B). It is not clear as to step c step of "is docked through the adsorbent to the substrate", especially in the absence of positive definition in the specification as to the term "dock".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27, 36, 38 and 44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 19 of U. S. Patent No. 6,225,047 ('047 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed method for identifying a translation

polynucleotide (i.e., polypeptide) in situ in an adsorbent wherein a polypeptide is determined by desorption spectrometry is encompassed by the '047 Patent. The '047 Patent is drawn to a method of identifying broadly analytes in the recited method steps. The determination of the analytes present in the sample is specifically the polypeptide recited in the instant method. (See the disclosure reciting the different embodiments of the claimed inventions.)

Claim 27 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U. S. Patent No. 5,719,060 ('060 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed method for identifying a translation polynucleotide (i.e., polypeptide) in situ in an adsorbent wherein a polypeptide is determined by desorption spectrometry is encompassed by the '060 Patent claiming similar method steps. The '060 Patent claims an analyte that encompasses the instant polypeptide.

Claims 27, 36 and 38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 and 10-11 and 19 of U. S. Patent No. 6,579,719 ('719 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other

because the instant claimed method for identifying a translation polynucleotide (i.e., polypeptide) in situ in an adsorbent wherein a polypeptide is determined by desorption spectrometry is similar to the process steps of the '719 Patent except for the analyte use. The '719 Patent is drawn to a method of identifying broadly analytes. The broad analytes encompasses the specific translation polynucleotide i.e., polypeptide of the instant method.

Claims 27, 36 and 38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5 of U. S. Patent No. 6,881,586 ('586 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed method for identifying a translation polynucleotide (i.e., polypeptide) in situ in an adsorbent wherein a polypeptide is determined by desorption spectrometry is encompassed by the '586 Patent. The '586 Patent is drawn to a method of identifying broadly analytes in the recited method steps. The determination of the analytes present in the sample is specifically the polypeptide recited in the instant method.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Little discloses a method based on mass spectrometric detection of translated target polypeptides.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 308-2439. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-3271 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. Wessendorf
Primary Examiner
Art Unit 1627

tdw
May 13, 2005